

Department of Veterans Affairs

Veterans Health Administration Pharmacy Benefits Management 1st Ave. – 1 Block North of Cermak Rd. Bldg. 37, Room 139 Hines, IL 60141

October 16, 2009 578/119D

Dear Manufacturer:

The following information is provided to assist your company in reporting the annual data mandated by Section 603 of Public Law 102-585 (Veterans Health Care Act of 1992; 38 U.S.C. 8126). Annual Non-Federal Average Manufacturers Price (NFAMP) calculations with 2010 Federal Ceiling Prices (FCP) for covered drugs are to be reported to Associate Chief Consultant, Pharmacy Benefits Management (PBM), on or before November 16, 2009. (Any anticipated changes in your company's method of accounting for charge backs, etc., must be implemented in accordance with Generally Accepted Accounting Principles (G.A.A.P.) and explained to the above office, the VA Office of General Counsel (025NAC), and the VA Office of Inspector General (55) no later than October 30, 2009).

Each covered drug's mandated FCP for 2010 (the second year of FSS multiyear contracts for statutory purposes) will be determined by adopting the lower of two calculation results. These two calculations are described in (1) 38 U.S.C 8126 (d) (1) and (2) 38 U.S.C. 8126 (d) (2), (a) (2) & (c). The same percent change in Consumer Price Index-Urban (CPIU), (when the change results from an increase) will be utilized in performing both calculations. This change in CPIU is identified as the percent change from September 2008 to September 2009. A negative or zero percent change will be read as no change in the CPIU. The U.S. Bureau of Labor Statistics data shows that the percent change to be -1.28%, which means that "0" (zero) will be used as the CPIU for the Federal Ceiling Price calculations due on November 16, 2009.

The one-half percent industrial funding fee (IFF) being incorporated into FSS contracts will not be included in calculations of non-FAMP or reporting of FCP, but will be included in the FSS selling price. Please see instructions from your contracting officer.

The Section 8126 (d) (1) calculation will begin with the <u>permanent</u> Federal Supply Schedule (FSS) contract price of a covered drug in effect on September 30, 2009. For those manufacturers that elected dual FSS pricing, the FSS contract price is the September 30, 2009 price <u>charged to other government agencies</u> and other authorized Schedule users, not the price paid by the Department of Veterans Affairs, Department of Defense (DoD), or Public Health Service (PHS)/Indian Health Service & Coast Guard. The appropriate FSS price will then be increased by the above percent change in CPIU to arrive at the 2010 FSS price cap. This cap applies to all "other user" FSS prices in 2010.

The Section 8126 (a) (2) & (c) calculation will begin with the 2009 annual non-FAMP computation; it will continue by multiplying that number by 0.76 and then subtracting any additional discount calculated based on a difference between "old" and "new" non-FAMPs. The lower of the above calculation and the 2010 FSS price cap will become the 2010 FCP. If there are "no sales" in a benchmark third quarter of a year that is used to derive the new NFAMP or old NFAMP, there can be no additional discount calculation for that particular item. In those cases, negative non-FAMPs should be reported and the additional discount will be entered as zero (0). If a covered drug had no reportable sales in 2009, its calculated 2010 FCP will be the 2009 FCP increased by an amount equal to the 2009 FCP multiplied by the 12-month percent change in CPI-U specified above or the FSS price effective September 30, 2009 multiplied by the CPI-U (FSS10max). The lower of the two will apply.

If they meet the other VA criteria, nominal prices excludable from non-FAMP's for 2009 calculations must be prices that are less than 10 percent of that particular items non-FAMP during the third quarter of 2008 (7/1/08 through 9/30/08). Where sales to end-users are required for calculation of non-FAMP due to the absence of wholesale sales, you need not include purchase by PHS grantees or disproportionate share hospitals ("covered entities") if the prices for those transactions were determined by PHS pursuant to Sect. 602 of the Veterans Health Care Act of 1992. Also, in figuring wholesale sales, you need not include the charge backs required to satisfy end-user purchases by the entities at prices determined by PHS under Sect. 602, or at prices set in negotiations with the PHS Section 602 pharmaceutical (PPV) and any subcontractors. However, sales to these entities at prices not negotiated by the Sect. 602 PPV and lower than Sect. 602 statutorily calculated prices must be included in NFAMP calculations. Finally, sales of specific inpatient covered drugs to disproportionate share hospitals at Sect. 602 prices may be excluded from NFAMP if you have properly obtained a "hold harmless letter" from VA (see July 8, 2004 Dear Manufacturer Letter).

VA must require that all wholesale sales (or direct sales where those are the proper beginning point) used for 2009 annual and 3rd quarter 2009 NFAMP reports (to be filed this November) be reduced by amounts reflecting TRICARE Retail Pharmacy Network (TRRx/T-Pharm) Flat File usage data posted or transmitted by DoD during the FY 2009 12-month reporting period, because the TRICARE usage constitutes sales to the Federal Government, pursuant to Section 703 of the 2008 National Defense Authorization Act. Manufacturers will use DoD's payment-due dates, as described below, to decide which TRRx usage may be ascribed to the relevant reporting periods. The same guidance will apply to all reports filed in 2010 and future years, assuming that DoD's Final Rule on Section 703 remains in effect.

Post Jan-2008 covered drug prescriptions (scrips) filled for TRICARE beneficiaries through the TRRx/T-Pharm Network should be treated by manufacturers as sales to the Federal Government, for NFAMP reporting purposes, <u>beginning on the payment-due date</u> transmitted by DoD to the manufacturer in the Flat File containing the manufacturer's quarterly DoD usage data and refund invoice.

The Secretary has exercised his administrative authority to excuse manufacturers from the obligation to correct and re-file any already submitted NFAMP report that did not take into account exclusion of TRRx Network covered drug script purchases identified by DoD in a Flat File transmission/posting after January 28, 2008 and before July 1, 2009. This re-filing waiver is applicable to every manufacturer, regardless of when or whether it actually paid DoD refunds/rebates for TRICARE script purchases during this time.

As an added service to streamline efficiency for the 2009 report, PBM is requesting that all NFAMP data be handled via e-mail. PBM will send your company's designated NFAMP representative (VIA E-MAIL) a file attachment in table format (.DBF). This attachment will contain all of your company's covered line items and certain pre-filled fields of data supplied by your company based on last year's Public Law. For example—we have provided the 2009 NFAMP Old (2008 NFAMP New which is the time period of 7/1/08 through 9/30/08) as well as your FSS price in effect on September 30, 2009 (FSS_09). We have also provided the Maximum FSS allowed for 2010 (FSS10MAX). Therefore, all that is required of your company is to furnish the 2009 Annual NFAMP (NFAMP_09) and NFAMP New (NFAMP_New) in the appropriate fields.

If you do not have access to e-mail, please notify the PBM, and we will mail out a diskette that contains all of your company's covered line items in Table format (.dbf). All that you need to run the diskette is access to a personal computer that has Microsoft Windows (versions 3.x, 95, 98, 2000, 2003 Server, XP or NT). For this year's Public Law submission, please submit line items under separate cover if you are reporting quarterly data or new product NFAMP along with your annual submission (that is-submit the items as separate files--no tabs in Excel).

After PBM receives your NFAMP data, we will calculate your {Change in NFAMP}, {Additional Discount}, and {2010 Federal Ceiling Price}. Pharmacy Benefits Management will send you an Excel file e-mail of your company's calculated 2010 Federal Ceiling Prices after the NFAMP data has been calculated. If we do not hear from your company within five workdays after we send the e-mail, we

will assume that you agree with VA's calculations of the federal ceiling prices. If there are changes to the data that PBM has provided in the pre-filled fields (e.g. Office of Inspector General (OIG) Audit recommendations), you have the option of changing the information on a separate electronic or hard copy submission. If your company elects to do so, you <u>must</u> submit a letter of explanation regarding all changes to the offices identified in paragraph one(above), no later than October 30, 2009. If you submit any corrected annual NFAMP reports after November 16, 2009, they must be reviewed and approved by VA OIG before being filed by PBM.

It is highly recommended and preferred that you submit your data in electronic format via the Pharmacy Benefits Management e-mail at MonFamp@va.gov. You may submit the data as you have in the past on the form provided using the instructional packet as a guide to the Public Law 102-585 compliance if you do not have access to a personal computer system.

All correspondence related to NFAMP calculations, FCP calculations, quarterly NFAMP reports, annual FCP reports, FCP reports for new products, FCP re-calculations for new products, corrections to quarterly NFAMP reports and correction to annual FCP report should be forward to:

Ted Karnezis
Pharmacy Benefits Management (119D)
1st Ave.-1 block north of Cermak Road
Bldg. 37, Room 139
Hines, Illinois 60141
e-mail: NonFamp@va.gov

The quarterly non-FAMP report for the third quarter of 2009 consists of the same data as the "new NFAMP" (7/1/09 to 9/30/09) reported on the annual calculation form from 2010 FCP's which is due by November 16, 2009. Consequently, it will not be necessary to submit the NFAMP third quarter 2009 Report separately. However, manufacturers that do not meet the November 16, 2009 annual reporting deadline will be subject to penalties for late data reporting as described in the Master Agreement, paragraph (IV) (B). Please note that 38 U.S.C. 8126 (e)(2) and Sect. 1927 (b)(3) of the Social Security Act (reflected in the Master Agreement) impose a civil money penalty on late reporting manufacturers in the amount of \$10,000.00 for each day in which required information has not been provided. VA asks that you submit the required annual data as soon as possible after the CPI-U change is posted in October and you receive this e-mail.

Section 8126(e) of the Law states that quarterly NFAMP reports are due 30 days after the end of the quarter. These figures should be as accurate as possible, since they serve as an indicator of pricing trends and will be used during Inspector General (IG) audits. Nevertheless, to assist manufacturers in providing the most accurate quarterly NFAMP calculations possible, the Pharmacy Benefits Management Section (PBM) will not seek imposition of late penalties for unreported data until 45 days after the end of each quarter. The same 45 day forbearance applies to filing Temporary and Permanent New Drug NFAMPs. Again, please note that each year the NFAMP third quarter data may be submitted as part of the Annual Report (which is due 45 days after the end of the third quarter).

After your company reports its annual 2009 NFAMP data via e-mail (or in the format on the enclosed diskette), the authorized official who signed your company's PPA addendum in 2009 (or an authorized successor) must prepare and sign a new PPA addendum, listing each covered drug and its 2010 FCP. This addendum should then be forwarded before December 1, 2009 to the VA National Acquisition Center (049A1F1), Building 37, First Avenue, 1 block North of Cermak Rd., P.O. Box 76, Hines, Illinois 60141.

If you have any questions about any of the above information, please call Ted Karnezis or John Weisman, at (708) 786-4387 or (708) 786-7878, respectively. You may also send your Public Law 2009 non-FAMP reports via facsimile to (708) 786-4386.

Sincerely,

Vincent S. Calabrese, Pharm.D. Associate Chief Consultant

Pharmacy Benefits Management Services

VACO Pharmacy Service

Enclosures:

Instructions for VHA's 2009 non-FAMP Report

Vincent Calabrese

Data Sheet (Excel format)

Instructions for VHA's 2009 non-FAMP report for 2010 PL 102-585 Due: Nov. 16, 2009

l.	Preparation Date	: [] [] - [] [] -
	Explanation:	The date the <u>report</u> is PREPARED. Format intended to be month-day-year. <i>Example:</i> 11/1/09 [PREP_DATE]
	Note	Page [] [] of [] []
	Explanation:	If hard copy report is provided, pages should be numbered to assure complete document is received. (Not part of electronic database submission, only used in hard copy paper submission).
2.	FDA Assigned L	abeler Code: [] [] []
	Explanation:	First segment of National Drug Code that identifies the manufacturer, labeler, re labeler, packager, repackager or distributor of the drug. Field is right justified and leading zeros are added to provide 5-digit code. [NDC_1].
3.	Product Code:	
	Explanation:	Second segment of the National Drug Code. Field is right justified and leading zeros are added to provide the 4-digit code. [NDC_2].
1.	Pkg. Code:	
	Explanation:	Third segment of the National Drug Code. field is right justified and leading zero is added if necessary to provide 2-digit code. [NDC_3].
5.	Units per Pkg.:	
	Explanation:	Number of units per package. <i>Example—bottles of 1000 tablets would be "1000"; liquid bottles of 473ML would be "473ML"; aerosol containers of 17.5GM would be "17.5GM"</i> . Maximum of 8 characters, free text. UNT_PKG]
5.	Date Entered Marl	ket: [] [] - [] []
	Explanation:	Date the specific product and package size (NDC) was <u>first commercially made available for sale.</u> This field is NOT mandatory for line items that entered the market before October 1992. Format intended to be month-day-year. <i>Example:</i> 12/02/99. [DATE_ENTER].
7.	Dosage Form:	
	Explanation:	Dosage form of the product. <i>Example: Capsules or CAP, Aerosol, Solution</i> . Field identification may be obtained from United States pharmacopoeia dispensing Information, Volume III, or you may provide the same 3-digit code used to identify "UNIT TYPE" provided to the Healthcare Finance Administration (HCFA). Maximum 12 characters, free text, [DOSE FORM].

8.	Strength:	
	Explanation:	Product Strength. <i>Example: 250MG; 325MG/5ML; etc.</i> Field identification may be obtained from United States Pharmacopoeia Dispensing Information, Volume III. Maximum 12 characters, free text. [STRENGTH].
9.	Product Name L	isted on FDA Application (limit 63 characters):
	Explanation:	This 63-character field is intended for entry of the product name as it appears on the FDA registration form. The filed is free text, left justified and limited to a maximum of 63 characters. [FDA_NAME].
10.	Trade Name (lim	nit 35 characters):
	Explanation:	This 35-character field is intended for entry of the product's patented trade name or brand name. The filed is free text, left justified and limited to a maximum of 35 characters. [TRADE_NAME]
11.	Generic Name (1	imit 35 characters):
	Explanation:	This 35-character field is intended for entry of the product's generic name. The filed is free text, left justified and limited to a maximum of 35 characters. [TRADE_NAME]
12.	% Increase in CF	PIU (Sept 08 – Sept 09): [_][_ <u>-</u>] [1_] 。 [2_] [8]
	Explanation:	The September 2008 and September 2009 Consumer Price Index-(CPI-U) can be obtained from the U.S. bureau of Labor Statistic or from the Pharmacy Benefits Management Section, telephone numbers indicated on page 3 of the cover letter. The percent increase in the CPI-U is calculated by multiplying the difference between the two index numbers by 100 and that product divided by the older (2008) of the two CPI-U's. This calculation is rounded to two decimal places. This field is numeric (5 charactersthis includes the decimal point and two decimal places). Rounding rules: After specified number of decimal places, if number is equal to or greater than 5, round up. If number is less than 5, round down. If there was no change or a negative change in the CPI-U, enter zero. [PCT_CPIU]
13.	2009 Federal Sup	pply Schedule Price: [_] [_] [_] [_] [_] [_] 。 [_] [_]
	Explanation:	The 2009 Federal Supply Schedule Price is the permanent contract price in effect or awarded on September 30, 2009 for single price companies. For manufacturers that selected dual FSS pricing, the 2009 Federal Supply Schedule Price is the September 30, 2009 awarded permanent contract price charged to other government agencies and authorized Schedule users—not the price paid by the Department of Veterans Affairs (VA), Department of Defense (DoD) or Public Health Service (PHS). DO NOT INCLUDE THE INDUSTRIAL FUNDING FEE (IFF) IN THIS CALCULATION. This field is numeric (10 characters—this includes the decimal point with the two decimal places). [FSS09]

14.		FSS Price per 38 U.S.C. 8126 (d)(1) owable CPIU Increase) [_] [_] [_] [_] [_] [_] [_]] [_]
	Explanation:	This price is determined by increasing the 2009 Federal Supply Schedule price by the allowable percent increase in CPIU. This price is defined in Section 38 U.S.C 8126 (d)(1). This field is numeric (10 characters—this includes the decimal point with two decimal places). [FSS10MAX]
15.	2009 Annual NF	AMP (10/01/08 – 09/30/09):
	Explanation:	The 2009 Annual Non-Federal Average Manufacturer's Price (NFAMP) is the weighted average manufacturers' sales price for that NDC line item. this is total non-Federal dollar sales (described by paragraphs I., J., N., O., and II.B.5. of the Master Agreement) for the period indicated (October 1, 2008 through September 30, 2009) divided by the total unit volume of sales for that NDC line item, excluding nominal priced sales and returned goods if records are available for verification. Dollar sales must reflect rebates, cash discounts, charge backs or other similar price reductions. This number is expressed in dollars and cents and should be rounded off using the rules in example 12. This field is numeric (10 characters—this includes the decimal point with two decimal places). [NFAMP_09]
16.	Old NFAMP (07	/01/08 – 09/30/08):
		[_] [_] [_] [_] [_] 。 [_] [_]
	Explanation:	The Old Non-Federal Average Manufacturer's Price is a weighted average manufacturer's sales price for that NDC line item. This is total non-Federal dollar sales for the period indicated (July 1, 2008 through September 30, 2008) divided by the total unit volume of sales for that NDC line item, excluding nominally priced sales and returned goods if records are available for verification. Dollar sale must reflect rebates, cash discounts, and charge backs. This number is expressed in dollars and cents and should be rounded off using the rules in example 12. This field is numeric (10 characters—this includes the decimal point with two decimal places). [NFAMP_OLD]
17.	New NFAMP (0	7/01/09 – 09/30/09)
		[_] [_] [_] [_] [_] [_] [_]
	Explanation:	The New Non-Federal Average Manufacturer's Price is a weighted-average manufacturer's sales price for that NDC line item. this is total non-Federal dollar sales for the period indicated (July 1, 2009 through September 30, 2009) divided by the total unit volume of sales for that NDC line item, excluding nominally price sales and returned goods if records are available for verification Dollar sales must reflect rebates, cash discounts, charge backs or other similar price reductions. This number is expressed in dollars and cents and should be rounded off using the rules in example 12. This figure also constitutes the Quarterly NFAMP report for the third quarter of 2009 (the third quarter's NFAMP Report submission date is November 15, 2009 to correspond with the Annual NFAMP reports). This field is numeric (10 characters—this includes the decimal point with two decimal places). [NFAMP_NEW]

18.	Change in NFAN	MP: [_] [_] [_] [_] [_] 。 [_]
	Explanation:	The Change in NFAMP is the difference between the New NFAMP (07/01/09 – 09/30-09) and the Old NFAMP (7/01/08 – 09/30/08). This number can be a negative number and is expressed in dollars and cents. This field is numeric (10 characters—this includes the decimal point with two decimal places). [NFAMP_CHG]
19.	Additional Disco	ount: [_] [_] [_] [_] [_] 。 [_]
	Explanation:	Additional Discount is the difference between the actual Change in NFAMP (Entry 18 on this form) and the legislative allowable increase. The allowable increase is the product of the Old NFAMP (Entry 16 on this form) and percent increase in CPI-U (Entry 12 on this form). The Additional Discount is expressed in dollars and cents and is always a positive number. If the change in NFAMP (Entry 18 on this form) is negative, then a 0.00 should be entered as the Additional discount. This field is numeric (10 characters—this includes the decimal point with two decimal places). [ADD_DISC]
	Example:	If Old NFAMP (Entry 16) =\$115.00
		New NFAMP (Entry 17) =\$121.00
		nnual NFAMP (Entry 15) =\$118.00
		t Increase in (CPI-U) (Entry 12) = "-1.28" or "0.00"
	Then Change in	NFAMP (Entry 18) = \$121.00 \$115.00 = \$6.00
Alla	owable increase is	s the product of Old NFAMP (Entry 16) and the percent increase in CPI-U.
Alle	owable increase =	= \$115.00 x (0.00)
_		\$0.00—no allowable increase!
For	•	
Ada	litional discount ((Entry 19) =
	Change	e in NFAMP (Entry 18) minus the Allowable Increase (Entry 12 x Entry 16)
In t	his example, Addi	itional discount = \$6.00 - \$0.00 = \$6.00.
20.	2010 Calculated	Ceiling per 38 U.S.C. 8126 (d)(2) and (a)(2)
	Explanation:	The calculation based on 38 U.S.C. 8126 (d)(2) and (a)(2) and (c) is the product of the 2009 Annual NFAMP (Entry 15) and 0.76 (as defined in legislation), less any Additional discount (Entry 19). This number is expressed in dollars and cents and should be rounded off using the rules in example 12. This field is numeric and can be a negative number (10 characters—this includes the decimal point with two decimal places). [CALCMAX10]
21.	2010 Federal Ce (Lowest of 38 U	iling Price [_] [_] [_] [_] [_] [_] .s.C. 8126(d)(1) or 38 U.s.C. 8126 (d)(2) & (a)(2))
	Explanation:	This figure is determined by taking the lower of fields 14 or 20. This field is numeric and can be a negative number (10 characters—this includes the decimal point with two decimal places). [FCP_2010]

22. 2010 FSS Contract Number [V][7][9][7][P]-[_][_][_][_]

Explanation: This is the FSS contract number assigned by the National Acquisition Center

(NAC) on September 30, 2009. The number normally consists of 1 alpha character, 3 numerics, 1 alpha character, 1 dash, four numerics and 1 alpha character. Typically, the 2009 FSS Contract Number begins with "V797P" and

the last 5 characters are unique for each company. [CNT_NO]

23. Company Official's Name:

Explanation: The name of the company official authorizing and certifying that the data

provided in this report is correct. This field is left justified and a maximum of

40 characters. [COMPANY_OF]

FORMAT OF 2009 NON-FAMP DATA RELATED TO 2010 PUBLIC LAW 102-585

The following data elements must be provided to the Pharmacy Benefits Managements Section (PBM) of the Veterans Health Administration:

Structure for database: NFAMP2010.DBF

Field	Field Name	Type	Width	Dec
1	PREP_DATE	Date	8	
2	NDC_1	Character	5	
3	NDC_2	Character	4	
4	NDC_3	Character	2	
5	UNT_PKG	Character	8	
6	DATE_ENTER	Date	8	
7	DOSE_FORM	Character	12	
8	STRENGTH	Character	12	
9	FDA_NAME	Character	63	
10	TRADE_NAME	Character	35	
11	GENERIC	Character	35	
12	PCT_CPIU	Numeric	5	2
13	FSS09	Numeric	10	2
14	FSS10MAX	Numeric	10	2 2 2 2 2 2 2 2
15	NFAMP_09	Numeric	10	2
16	NFAMP_OLD	Numeric	10	2
17	NFAMP_NEW	Numeric	10	2
18	NFAMP_CHG	Numeric	10	2
19	ADD_DISC	Numeric	10	2
20	CALCMAX10	Numeric	10	2
21	FCP_2010	Numeric	10	2
22	CNT_NO	Character	11	
23	COMPANY_OF	Character	40	
Total **			339	

PLEASE NOTE: Page Numbers are not required in the electronic submission structure.

The database format is compatible with DBASE III Plus, FoxPro, Visual FoxPro, Quick Silver, DBXL or equivalent (*.DBF) and is to be provided through direct electronic communications (e-mail). To expedite the electronic transmissions, the data may be compressed using PKZIP for data submissions larger than 4MB.

Please do not submit data using a comma delimiter (ASCII) format. Any changes from the original format will be returned to issuer to complete correctly.

Please note that the PBM electronic bulletin board dial-in server has been discontinued. Electronic submission may be accomplished via e-mail to NonFamp@va.gov. If electronic submission is not possible, data may be submitted on diskette or manually. (Form. OMB NO. 2900-3093 rev 9/09) enclosed to:

Ted Karnezis
Public Law Database Manager
Pharmacy Benefits Management (119D)
1st Ave.-1 Block North of Cermak Rd.
Bldg. 37, Room 139
Hines, Il 60141

For contract questions, you may contact Cheryl Ward-Roberts or your contracting officer, at the National Acquisition Center, Pharmaceutical Products Division: (708)-786-5180.

Preparation Date: ¹ [] [] - [] [] - [] [] 3 [] [] [] [] 4 [] []		Veterans Health Administration NFAMP Report for Public Law 102-585 (For Pharmaceutical Pricing Agreements - 2010) FDA Assigned Labeler Code: 2[][][][][][] 5[][][][][][][][][][][]	Administration ublic Law 102-585 Ig Agreements - 2010) e: 2[][][][][][]	Page: □□ of □□□
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Company Official's Name Authorizing and Certifying the accuracy of this report (limit 40 characters)	d Certifying the accuracy of	this report (limit 40 cha	racters)	OMB no. 2900-0393 (Rev. 9/09)